510(k) Premarket Notification Summary

JAN 20 1999

K982532

1• Sponsor :

SOFRADIM PRODUCTION S.a.
197, avenue Théodore Braun - 69400 Villefranche sur Saône - FRANCE
Tel. : +33- 4 74 60 03 27 - Fax : +33- 4 74 60 03 66

Contact Person : François-Régis ORY, PhD
President

Date of Summary Preparation : October 28, 1997

2 • Device Name :

Trade Name : PARIETEX®
Common/Usual Name : PET Surgical Mesh
Classification Name : Surgical Mesh

3 • Identification of the Predicate or Legally Marketed Devices to Which Equivalence is being claimed :

- *Mersilene®*, (Ethicon, Johnson & Johnson)
- *Ercylene®*, (Davis & Geck)
- *Prolene®* , (Ethicon, J & J)
- *Surgipro®*, (U.S.S.C.)
- *Marlex®, Visilex®* (Bard - Davol)
- *Atrium®* , (Atrium)

4 • Device Description :

Mesh made of Biocompatible, knitted multifibre polyester (PET). Each mesh is supplied sterile and nonpyrogenic in a single-use package.

5 • Intended Use :

The Parietex® meshes has the same intended use as the predicate devices :

- reinforcement of tissue during surgical repair

6 • Indications Statement :

The Parietex® meshes has the same indications as the predicate devices :

- repair of inguinal hernias, incisional hernias and rectal and apical prolapses

7 •- Mechanical properties :

COMPARATIVE TABLE		PARIETEX® (Polyester)	MERSILENE® (Polyester)	PROLENE® (Polypropylene)	MARLEX® (Polypropylene)
Thread Resistance [N]	Chain	68.5	15.2	57	57.2
	Weft	55.4	15.5	74.6	55.8
Tear Resistance [daN]	Chain	3.36	0.64	<0.1	0.66
	Weft	2.78	0.68	4.41	4.03
Breaking Resistance [daN]	Chain	39.11	20.53	59.74	43.2
	Weft	63.6	10.04	76.74 :	56.7

Source : U. Klinge, J. Conze, B. Klosterhalfen, W. Limberg, B. Obolenski, A.P. Öttinger, V. Schumpelick : "Alteration of abdominal wall mechanics after mesh implantation. Experimental alteration of mesh stability. Langenbecks - Archiv für Chirurgie, Band 381 Heft 6, 1996

8 • Performance Data

8.1 Biocompatibility Tests

Standard biocompatibility testing was performed according to the ISO 10993 - 1 Standards and FDA requirements.

The device passed all of the following biocompatibility tests :

- Cytotoxicity
- Systemic toxicity
- Intracutaneous toxicity
- Sensitization
- Mutagenicity tests :
  - Ames's test
  - Chromosomal aberration
  - Sister chromatid exchange
- Implantation tests :
  - Short term implantation
  - Long term implantation

All tests were performed according to GLP in an American Laboratory.

8.2 Clinical tests

"Laparoscopic and open abdominal wall reconstruction using PARIETEX® meshes " • Clinical results on 2,700 hernias.
(Paper accepted by "HERNIA" 1998)

Summary :

The authors report a series of 2,445 inguinal hernias and 272 incisional hernias treated between 1993 and 1997 by the insertion of a Parietex® mesh via either a laparoscopic (1,595 procedures) or an open approach (578 procedures). Pain scores and time to return to normal activity were lower in the laparoscopic group than in the open surgery group ($p<0.001$). In all of the groups, the average incidence of the total reported events (complications) was around 10 % with no statistical difference. This ratio seemed to compare favourably to previously published reports. Considering inguinal hernias in particular, chronic pains was extremely rare (0.6 % in the laparoscopic group and 0.8 % in the open surgery group). Whatever the approach was, sepsis was also very rare (1/1526 laparocopic procedures, 2/380 open operations). These findings illustrate the local tolerance of the mesh. Recurrence rates were below 1 % with no statistical difference between groups. This retrospective study demonstrates the clinically apparent local tolerance of this type of mesh. Prospective and long term clinical results will be necessary to demonstrate that the optimized short term tolerance of Parietex® mesh will influence the long term functional results.

"Laparocopic Hernia Repair • Total Extra-Peritoneal Approach • Experience in 1,200 Hernia Repair". Complete Litterature Review.
S. Benchetrit, M.D. - Clinique Jeanne d'Arc, LYON (FRANCE).
(Paper accepted by "Surgical Endoscopy" 1998)

Summary :

We report our experience with 1,200 consecutive hernia repair by total extra-peritoneal approach. Between November 1993 and the end of September 1997, 1,200 hernias have been repaired using the extra-peritoneal approach with a balloon trocar in our center.
A balloon dissector was used to dissect the extra-peritoneal space in all patients. A 15 x 10 cm mesh was used. There were no visceral complication, no early recurrence and no sepsis. The follow up was from 3 to 36 months in 90 % of the patients with a low recurrence rate (0.8 %). One patient needed to be reoperated for chronic pain. Return to normal activity was 1-3 days. Surgical cost was compensed by social cost savings due to a shorter hospital stay and a quicker return to normal activity compared to open hernia repair. The early results of this technique experienced during this short study have been encouraging.

9 • Conclusions drawn from the preclinical and clinical testing

The Parietex® meshes are substancially equivalent to the predicate devices because they have the same intended use, very similar indications, principles of operation, and technological characteristics, and any difference in the Parietex® meshes's technological characteristics do not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 1999

Sofradim Productions
c/o Mr. Howard M. Holstein
Hogan & Hartson
555 Thirteenth Street, Northwest
Washington, D.C. 20004

Re: K982532
Trade Name: Parietex® Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: December 4, 1998
Received: December 4, 1998

Dear Mr. Holstein:

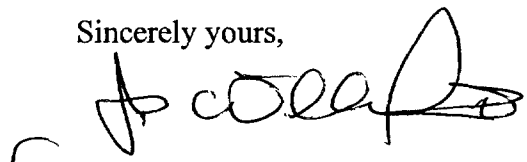
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982532

Device Name: Parietex ®

Indications For Use:

-- Parietex ® TEC, TET, TECR = Inguinal hernias and Incisional hernias

-- Parietex ® TEL = Incisional hernias

-- Parietex ® TEC (folding meshes)/TECT (folding mesh)/ = Inguinal hernias
1410P, 1410PS, 1410DP, 1610P, 1510 ADP
1510 ADP2

-- Parietex ® TEC GK03, GK04, GK05 = Rectal and Apical genital prolapses

-- Parietex ® TECR (folding mesh) = Inguinal hernias
1410 DP2

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982532

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)